OFFICE OF THE GENERAL COUNSEL Nevada State Board of Medical Examiners 9600 Gateway Drive Reno, Nevada 89521 7751, 688-2559

BEFORE THE BOARD OF MEDICAL EXAMINERS OF THE STATE OF NEVADA

* * * * *

In the Matter of Charges and) Case	No. 18-31555-1
Complaint Again))	FILED
NIKOLAOS JOHN TSIOURIS, M.D.,))	AUG 2 4 2018
Respondent.) NI) By:_	EVADA STATE BOARD OF MEDICAL EXAMINERS

COMPLAINT

The Investigative Committee¹ (IC) of the Nevada State Board of Medical Examiners (Board) hereby issues this formal Complaint (Complaint) against Nikolaos John Tsiouris, M.D. (Respondent), a licensed physician in Nevada. After investigating this matter, the IC has a reasonable basis to believe that Respondent has violated provisions of Nevada Revised Statutes (NRS) Chapter 630 and Nevada Administrative Code (NAC) Chapter 630 (collectively, the Medical Practice Act).

The IC alleges the following facts:

- 1. Respondent is currently licensed in active status (License No. 11945), and has been licensed as a physician by the Board since July 10, 2006, pursuant to the provisions of the Medical Practice Act.
- 2. Patient A was a 67-year-old male at the time of the events at issue. His true identity is not disclosed herein to protect his privacy, but is disclosed in the Patient Designation served upon Respondent along with a copy of this Complaint.

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¹ The Investigative Committee of the Nevada State Board of Medical Examiners, at the time the filing of this Complaint was approved, was composed of Board members Theodore B. Berndt, M.D., Wayne Hardwick, M.D., and Mr. M. Neil Duxbury.

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	3.	On or abou	at June 2	2, 2013, Patient A	presented	to Unive	rsity Med	dical Cen	ter, in Las
Vegas	, Neva	da (UMC)	with a	malfunctioning	Biotronik	Lumax	CRT-D	device,	originally
impla	nted in o	or about Sep	tember	2009.					

- On or about June 3, 2013, Respondent performed an implantable cardioverter-4. defibrillator (ICD) generator explant, right ventricular lead implant, pocket revision, biventricular ICD generator implant, and electrophysiologic evaluation defibrillation threshold (DFT) testing.
- The new implant was a device manufactured and sold by St. Jude Medical Unify 5. Assura.
- Respondent implanted the ICD improperly by installing the electrical leads in 6. reverse order.
- Respondent did not personally perform the intraoperative or postoperative testing, 7. rather he relied on other personnel from St. Jude Medical Unify Assura for the testing of Patient A, and did not verify the results.
- Respondent did not adequately supervise the personnel from St. Jude Medical 8. Unify Assura for the intraoperative or postoperative testing of Patient A.
 - Patient A was discharged the following day by another physician. 9.
- Patient A presented for a follow up outpatient appointment on or about June 26, 10. 2013, and Respondent reported no complications. Respondent checked the incision, removed Patient A's staples, and provided incision care instructions, but did not perform a test of the implant.
- Respondent scheduled an appointment for device interrogation and reprogramming 11. approximately two weeks from the June 26, 2013 appointment, but Patient A did not present for this appointment, as Patient A chose to seek treatment from a new cardiologist.
- After the appointment on June 26, 2013, Respondent did not have further contact 12. with Patient A.
- As a result of Respondent's failure to install the implant properly, Patient A had to 13. have an additional surgery, three months later, to correct Respondent's error.

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- On or about August 30, 2013, Patient A had surgery to correct the implanted ICD, 14. improperly implanted by Respondent.
 - Respondent's transpositioning of the leads caused the ICD implant to malfunction. 15.
- The cardiologist who fixed the improper implant had to reposition the 16. malpositioned right atrial and left ventricular transvenous automatic implantable cardioverter defibrillator leads, and remove the chronic right ventricular transvenous endocardial defibrillation catheter.

COUNT I

Malpractice - Failure to Perform With Reasonable Care When Performing Operation NRS 630.301(4)

- All of the allegations in the above paragraphs are hereby incorporated by reference 17. as though fully set forth herein.
- NRS 630.301(4) provides that malpractice is an act, among others, that constitutes 18. grounds for initiating disciplinary action.
- Malpractice is defined as "the failure of a physician, in treating a patient, to use the 19. reasonable care, skill, or knowledge ordinarily used under similar circumstances." NAC 630.040.
- Respondent failed to use reasonable care, skill, or knowledge ordinarily used under 20. the circumstances by, including, but not limited to, alone, or in combination, failing to connect the ICD implant properly, failing to double check the serial numbers with the connections, failing to personally perform the intraoperative and postoperative testing to detect his error, failing to recognize that the intraoperative and postoperative testing on the leads were not normal, and by relying on others to perform these tests without verifying their results.
- As a direct result of Respondent's failure to use reasonable care, skill, or 21. knowledge ordinarily used in the circumstances, Patient A was required to undergo a second surgery to address the improperly implanted device.
- By reason of the foregoing, Respondent is subject to discipline by the Board as 22. provided in NRS 630.352.

OFFICE OF THE GENERAL COUNSEL Nevada State Board of Medical Examiners 9600 Gareway Drive Reno, Nevada 89521

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COUNT II

Failure to Adequately Supervise

Patient A - NRS 630.306(1)(r)

- 23. All of the allegations in the above paragraphs are hereby incorporated as if fully set forth herein.
- 24. NRS 630.306(1)(r) provides that a failure to adequately supervise a medical assistant pursuant to the regulations of the Board is an act that constitutes grounds for initiating disciplinary action.
- 25. By the conduct described herein, Respondent failed to adequately supervise the personnel from St. Jude Medical Unify Assura in their performance of intraoperative or postoperative testing of Patient A.
- 26. By reason of the foregoing, Respondent is subject to discipline by the Nevada State Board of Medical Examiners as provided in NRS 630.352.

COUNT III

Failure to Maintain Legible Medical Records

Patient A - NRS 630.3062(1)(a)

- 27. All of the allegations in the above paragraphs are hereby incorporated by reference as though fully set forth herein.
- 28. NRS 630.3062(1)(a) provides that the failure to maintain timely, legible, accurate and complete medical records relating to the diagnosis, treatment and care of a patient constitutes grounds for initiating disciplinary action.
- 29. Respondent failed to maintain timely, legible, accurate and complete medical records/notes relating to the diagnosis, treatment, and care of Patient A.
- 30. By reason of the foregoing, Respondent is subject to discipline by the Board as provided in NRS 630.352.

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WHEREFORE, the Investigative Committee prays:

- 1. That the Board give Respondent notice of the charges herein against him and give him notice that he may file an answer to the Complaint herein as set forth in NRS 630.339(2) within twenty (20) days of service of the Complaint;
- 2. That the Board set a time and place for a formal hearing after holding an Early Case Conference pursuant to NRS 630.339(3);
- 3. That the Board determine the sanctions it will impose if it finds Respondent violated the Medical Practice Act;
- 4. That the Board make, issue and serve upon the Respondent, in writing, its findings of fact, conclusions of law and order, which shall include the sanctions imposed; and
- 5. That the Board take such other and further action as may be just and proper in these premises.

DATED this 24 day of August, 2018.

INVESTIGATIVE COMMITTEE OF THE NEVADA STATE BOARD OF MEDICAL EXAMINERS

By:

Donald K. White, Esq.

Deputy General Counsel for the Board Attorney for the Investigative Committee

OFFICE OF THE GENERAL COUNSEL Nevada State Board of Medical Examiners

VERIFICATION

STATE OF NEVADA		SS
COUNTY OF WASHOE)	33

Wayne Hardwick, M.D., hereby deposes and states under penalty of perjury under the laws of the state of Nevada that he is the Chairman of the Investigative Committee of the Nevada State Board of Medical Examiners that authorized the foregoing Complaint against the Respondent herein; that he has read the foregoing Complaint; and based upon information discovered during the course of the investigation into a complaint against Respondent, he believes the allegations and charges in the foregoing Complaint against Respondent are true, accurate and correct.

Dated this 24H day of August, 2018.

Wayne Hardwick, M.D.

Marye Hardwick